(1) the term ''genetically targeted drug'' means a drug that—

(A) is the subject of an application under section 355(b)(1) of this title or section 351(a) of the Public Health Service Act [42 U.S.C. 262(a)] for the treatment of a rare disease or condition (as such term is defined in section 360bb of this title) that is serious or life-threatening;

(B) may result in the modulation (including suppression, up-regulation, or activation) of the function of a gene or its associated gene product; and

(C) incorporates or utilizes a genetically targeted technology;

(2) the term ''genetically targeted technology'' means a technology comprising non-replicating nucleic acid or analogous compounds with a common or similar chemistry that is intended to treat one or more patient subgroups, including subgroups of patients with different mutations of a gene, with the same disease or condition, including a disease or condition due to other variants in the same gene; and

(3) the term ''variant protein targeted drug'' means a drug that—

(A) is the subject of an application under section 355(b)(1) of this title or section 351(a) of the Public Health Service Act [42 U.S.C. 262(a)] for the treatment of a rare disease or condition (as such term is defined in section 360bb of this title) that is serious or life-threatening;

(B) modulates the function of a product of a mutated gene where such mutation is responsible in whole or in part for a given disease or condition; and

(C) is intended to treat one or more patient subgroups, including subgroups of patients with different mutations of a gene, with the same disease or condition.

(d) Rule of construction

Nothing in this section shall be construed to—

(1) alter the authority of the Secretary to approve drugs pursuant to this chapter or section 351 of the Public Health Service Act [42 U.S.C. 262] (as authorized prior to December 13, 2016), including the standards of evidence, and applicable conditions, for approval under such applicable chapter or Act; or

(2) confer any new rights, beyond those authorized under this chapter or the Public Health Service Act [42 U.S.C. 201 et seq.] prior to December 13, 2016, with respect to the permissibility of a sponsor referencing information contained in another application submitted under section 355(b)(1) of this title or section 351(a) of the Public Health Service Act [42 U.S.C. 262(a)].

(June 25, 1938, ch. 675, §529A, as added Pub. L. 114–255, div. A, title III, §3012, Dec. 13, 2016, 130 Stat. 1091.)

Editorial Notes

REFERENCES IN TEXT

The Public Health Service Act, referred to in subsec. (d)(2), is act July 1, 1944, ch. 373, 58 Stat. 682, which is classified generally to chapter 6A (§201 et seq.) of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 201 of Title 42 and Tables.

PART C—ELECTRONIC PRODUCT RADIATION CONTROL

Editorial Notes

CODIFICATION

This part was classified to subpart 3 (§263c et seq.) of part F of subchapter II of chapter 6A of Title 42, The Public Health and Welfare, prior to its renumbering by Pub. L. 101–629, §19(a)(4), Nov. 28, 1990, 104 Stat. 4530, as amended by Pub. L. 103–80, §4(a)(2), Aug. 13, 1993, 107 Stat. 779.

§360hh. Definitions

As used in this part—

(1) the term ''electronic product radiation'' means—

(A) any ionizing or non-ionizing electromagnetic or particulate radiation, or

(B) any sonic, infrasonic, or ultrasonic wave, which is emitted from an electronic product as the result of the operation of an electronic circuit in such product;

(2) the term ''electronic product'' means (A) any manufactured or assembled product which, when in operation, (i) contains or acts as part of an electronic circuit and (ii) emits (or in the absence of effective shielding or other controls would emit) electronic product radiation, or (B) any manufactured or assembled article which is intended for use as a component, part, or accessory of a product described in clause (A) and which when in operation emits (or in the absence of effective shielding or other controls would emit) such radiation;

(3) the term ''manufacturer'' means any person engaged in the business of manufacturing, assembling, or importing of electronic products;

(4) the term ''commerce'' means (A) commerce between any place in any State and any place outside thereof; and (B) commerce wholly within the District of Columbia; and

(5) the term ''State'' includes the District of Columbia, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, Guam, and American Samoa.

(June 25, 1938, ch. 675, §531, formerly act July 1, 1944, ch. 373, title III, §531, formerly §355, as added Pub. L. 90–602, §2(3), Oct. 18, 1968, 82 Stat. 1174; amended Pub. L. 94–484, title IX, §905(b)(1), Oct. 12, 1976, 90 Stat. 2325; renumbered §531 and amended Pub. L. 101–629, §19(a)(1)(B), (3), (4), Nov. 28, 1990, 104 Stat. 4529, 4530; Pub. L. 103–80, §4(a)(2), Aug. 13, 1993, 107 Stat. 779.)

Editorial Notes

CODIFICATION

Section was classified to section 263c of Title 42, The Public Health and Welfare, prior to renumbering by Pub. L. 101–629.

AMENDMENTS

1993—Pub. L. 103–80 amended directory language of Pub. L. 101–629, §19(a)(4), which renumbered section 263c of Title 42, The Public Health and Welfare, as this section.

1990—Pub. L. 101–629, §19(a)(1)(B), substituted ''this part'' for ''this subpart'' in introductory provisions.

1976—Par. (5). Pub. L. 94–484 defined ''State'' to include Northern Mariana Islands.

Statutory Notes and Related Subsidiaries

SHORT TITLE

For short title of Pub. L. 90–602, which enacted provisions now comprising this part (§§360hh to 360ss), as the ''Radiation Control for Health and Safety Act of 1968'', see section 1 of Pub. L. 90–602, set out as a Short Title of 1968 Amendments note under section 301 of this title.

TRANSFER OF SUBPART; CONSTRUCTION

Pub. L. 101–629, §19(c), Nov. 28, 1990, 104 Stat. 4530, provided that: ''The transfer of subpart 3 of part F of title III of the Public Health Service Act [42 U.S.C. 263b et seq.] to the Federal Food, Drug, and Cosmetic Act [this chapter] does not change the application of the requirements of such subpart and such Act to electronic products which were in effect on the date of the enactment of this Act [Nov. 28, 1990].''

DEFINITION OF ''SECRETARY'' AND ''DEPARTMENT''

Pub. L. 90–602, §3, Oct. 18, 1968, 82 Stat. 1186, as amended by Pub. L. 96–88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695, provided that: ''As used in the amendments made by section 2 of this Act [enacting provisions now comprising sections 360hh to 360ss of this title], except when otherwise specified, the term 'Secretary' means the Secretary of Health and Human Services, and the term 'Department' means the Department of Health and Human Services.''

NONINTERFERENCE WITH OTHER FEDERAL AGENCIES

Pub. L. 90–602, §4, Oct. 18, 1968, 82 Stat. 1187, provided that: ''The amendments made by section 2 of this Act [enacting provisions now comprising sections 360hh to 360ss of this title] shall not be construed as superseding or limiting the functions, under any other provision of law, of any officer or agency of the United States.''

§ 360ii. Program of control

(a) Establishment

The Secretary shall establish and carry out an electronic product radiation control program designed to protect the public health and safety from electronic product radiation. As a part of such program, he shall—

(1) pursuant to section 360kk of this title, develop and administer performance standards for electronic products;

(2) plan, conduct, coordinate, and support research, development, training, and operational activities to minimize the emissions of and the exposure of people to, unnecessary electronic product radiation;

(3) maintain liaison with and receive information from other Federal and State departments and agencies with related interests, professional organizations, industry, industry and labor associations, and other organizations on present and future potential electronic product radiation;

(4) study and evaluate emissions of, and conditions of exposure to, electronic product radiation and intense magnetic fields;

(5) develop, test, and evaluate the effectiveness of procedures and techniques for minimizing exposure to electronic product radiation; and

(6) consult and maintain liaison with the Secretary of Commerce, the Secretary of Defense, the Secretary of Labor, the Atomic Energy Commission, and other appropriate Federal departments and agencies on (A) techniques, equipment, and programs for testing and evaluating electronic product radiation, and (B) the development of performance standards pursuant to section 360kk of this title to control such radiation emissions.

(b) Powers of Secretary

In carrying out the purposes of subsection (a), the Secretary is authorized to—

(1)(A) collect and make available, through publications and other appropriate means, the results of, and other information concerning, research and studies relating to the nature and extent of the hazards and control of electronic product radiation; and (B) make such recommendations relating to such hazards and control as he considers appropriate;

(2) make grants to public and private agencies, organizations, and institutions, and to individuals for the purposes stated in paragraphs (2), (4), and (5) of subsection (a) of this section;

(3) contract with public or private agencies, institutions, and organizations, and with individuals, without regard to section 3324 of title 31 and section 6101 of title 41; and

(4) procure (by negotiation or otherwise) electronic products for research and testing purposes, and sell or otherwise dispose of such products.

(c) Record keeping

(1) Each recipient of assistance under this part pursuant to grants or contracts entered into under other than competitive bidding procedures shall keep such records as the Secretary shall prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such assistance, the total cost of the project or undertaking in connection with which such assistance is given or used, and the amount of that portion of the cost of the project or undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(2) The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of the recipients that are pertinent to the grants or contracts entered into under this part under other than competitive bidding procedures.

(June 25, 1938, ch. 675, §532, formerly act July 1, 1944, ch. 373, title III, §532, formerly §356, as added Pub. L. 90–602, §2(3), Oct. 18, 1968, 82 Stat. 1174; renumbered §532 and amended Pub. L. 101–629, §19(a)(1)(B), (2)(A), (3), (4), Nov. 28, 1990, 104 Stat. 4529, 4530; Pub. L. 103–80, §4(a)(2), Aug. 13, 1993, 107 Stat. 779.)

Editorial Notes

CODIFICATION

In subsec. (b)(3), ''section 6101 of title 41'' substituted for ''section 3709 of the Revised Statutes of the United States (41 U.S.C. 5)'' on authority of Pub. L. 111–350, §6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

Section was classified to section 263d of Title 42, The Public Health and Welfare, prior to renumbering by Pub. L. 101–629.